Remarks/Arguments:

Claims 1, 6, 8-12, and 25-26 are pending in the application and were examined. Claims 1 and 25 are amended herein, without the addition of new matter. Support for the amendments can be found throughout the specification, for example, page 7, line 7, page 7, line 20, and page 8, line 2. Claim 27 is newly added as supported by claim 1 and page 32, lines 16-21.

35 U.S.C. §112, first paragraph

Claims 1, 6, 8-12, and 25-26 are rejected for failing to comply with the written description requirement for reciting "not more than" 15% excipients, and for reciting "not more than" 1% lipids. In addition, the Office Action states that the specification does not recite "1% (w/v)" of lipids.

The amended claims replace "not more than" with "less than" as supported in the specification. With respect to "1% (w/v)" of lipids, page 7, line 7 indicates the formulations are "substantially free" of lipids, and page 7, line 20, defines "substantially free" further to include "less than about 1%." Accordingly, the application describes the subject matter, and Applicants respectfully urge withdrawal of the rejection.

35 U.S.C. §112, second paragraph

Claims 1, 6, 8-12, and 25-26 are alleged to be indefinite for term "not more than 15%" of excipients. The Office Action alleges that a lower limit is not apparent, and the claim could encompass 99% excipients. Applicants have amended the claims to even more clearly recite that the composition comprises less than 15% (w/v) excipients. Withdrawal of the rejection is requested.

35 U.S.C. §103(a)

Claims 1-6 and 8-14 are rejected as obvious over U.S. 4,452,817 (Glen) and U.S. 7,166,303 (Meadows). The Office Action suggests that one of skill in the art would arrive at the claimed amount of excipients by routinely optimizing the amount used in the Glen, and that Meadows supplies various aspects of the dependent claims not found in Glen. Applicants traverse the rejection as failing to establish *prima facie* obviousness on at least two grounds.

The Office Action cites to Example 10a of Glen as teaching 10% polyethylene glycol. Example 10a, however, includes 10% propylene glycol and not polyethylene glycol as claimed.

The Office Action thus failed to ascertain the differences between the prior art and the claims as required. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

The Office Action also takes the position that the skilled artisan could optimize the composition parameters (10% poloxamer 188 and 10% propylene glycol) of Glen's Example 10a to obtain the claimed range of excipients. But, a particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); MPEP 2144.05 II(B).

The Office Action has not shown that Glen or Meadows recognized the result-effectiveness of the claimed excipients or their combination, or provided any explanation based on scientific reasoning that those of skill in the art would have considered it obvious to optimize Example 10a by lowering the levels of poloxamer 188 and propylene glycol while maintaining minimal lipid. In fact, Glen suggests that significant quantities of lipid are required where low concentrations of co-solvents are used, see, *e.g.*, Example 9, and Meadows suggests that poloxamer 188 by itself can maximally solubilize 0.8% propofol, see, *e.g.*, Table 2.

The Office Action has not met its burden to establish a result-effective nexus. Lacking this nexus, the skilled artisan has no basis to optimize the poloxamer and/or polyethylene glycol concentration. Withdrawal of the rejection is requested.

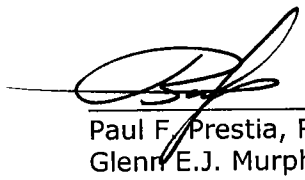
Double Patenting

Claims 1, 6, 8-12, and 25-26 are provisionally rejected for alleged obviousness-type double patenting over copending application 10/677,747. Applicants will address the rejection upon an indication of allowable subject matter, and request continued abeyance.

Conclusion

Applicants request entry of the amendments submitted herewith, and reconsideration of the various rejections in view of the amendments and remarks. Upon such reconsideration, Applicants respectfully submit that all claims should be found allowable and notification thereof is earnestly solicited.

Respectfully submitted,



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